

**Title 14**  
**INDEPENDENT AGENCIES**  
**Subtitle 01 PRESCRIPTION DRUG AFFORDABILITY BOARD**  
**14.01.02 Prescription Drug Affordability Fund**  
Authority: Health-General Article, §21–2C–11, Annotated Code of Maryland

**Notice of Emergency Action**

[21-204-E]

The Joint Committee on Administrative, Executive, and Legislative Review has granted emergency status to amendments to Regulations .02 and .03 under **COMAR 14.01.02 Prescription Drug Affordability Fund**.

**Emergency status began: November 16, 2021.**  
**Emergency status expires: May 6, 2022.**

**Comparison to Federal Standards**

There is no corresponding federal standard to this emergency action.

**Estimate of Economic Impact**

**I. Summary of Economic Impact.** Pursuant to Health-General Article, §21–2C–11, Annotated Code of Maryland, the Board collects an annual assessment. If the current assessment of \$1,000 exceeds 1 percent of an entity’s Maryland revenue, the entity may seek a waiver of the assessment. These emergency regulations clarify the procedures for obtaining a waiver, and establish procedures for obtaining an exemption for those entities not covered by the statute and for paying an assessment in installments. Applying for the waiver or exemption may impose minimal administrative burdens on businesses and minimal administrative burdens on the Board in determining those requests. The Board estimates there may be a slight decrease in revenue due to the granting of the qualified waivers or exceptions, but the realized revenue is anticipated to fall within the previously estimated range of \$750,000 to \$1,500,000. This revenue is the only source of funding for the Board’s operation. The proposed action does not impose a mandate on a local government unit.

<b>II. Types of Economic Impact.</b>	Revenue (R+/R-)	Expenditure (E+/E-)	Magnitude
A. On issuing agency:	NONE		
B. On other State agencies:	NONE		
C. On local governments:	NONE		
	Benefit (+)		Magnitude
	Cost (-)		

D. On regulated industries or trade groups:

Prescription Drug Affordability Fund assessment	(+)	Nominal
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E. On other industries or trade groups: NONE

F. Direct and indirect effects on public: NONE

**III. Assumptions.** (Identified by Impact Letter and Number from Section II.)

D. Pursuant to Health-General Article, §21–2C–11, Annotated Code of Maryland, the Board collects an annual assessment. If the current assessment of \$1,000 exceeds 1 percent of an entity’s Maryland revenue, the entity may seek a waiver of the assessment. These emergency regulations clarify the procedures for obtaining a waiver, and establish procedures for obtaining an exemption for those entities not covered by the statute and for paying an assessment in installments. Applying for the waiver or exemption may impose minimal administrative burdens on businesses and minimal administrative burdens on the Board in determining those requests. Entities will be able to seek a waiver or exemption from the annual assessment. The Board estimates there may be savings for individual entities due to the granting of the qualified waivers or exceptions, but the expected costs for the regulated industries is anticipated to fall within the previously estimated range of \$750,000 to \$1,500,000 established when promulgating existing COMAR 14.01.02.

### Economic Impact on Small Businesses

The emergency action has minimal or no economic impact on small businesses.

**.02 [Assessment of Entities, Notification of Assessment] Invoice, Exemption, Waiver, and Collection [of Fees].**

A. [The Board shall collect an annual assessment from the entities identified in Health-General Article, §21–2C–11, Annotated Code of Maryland, and specified in Regulation .03 of this chapter.] *In each State fiscal year, the Board shall issue an invoice to each entity identified in Health-General Article §21–2C–11, Annotated Code of Maryland, and Regulation .03 of this chapter and collect an annual assessment.*

B. [No later than July 15, 2021, and July 15 of every year thereafter, the Board shall issue a notification to these entities of their obligation to pay the annual assessment.] *Exemption from Assessment.*

(1) *An entity may request an exemption from the annual assessment by submitting a completed exemption form to the Board within 30 days of the Board transmitting the assessment invoice.*

(2) *The exemption form shall be executed under oath and attest that:*

(a) *The entity is not a qualifying entity as defined in COMAR 14.01.01 and Health-General Article, §21-2C-11(b)(1), Annotated Code of Maryland;*

(b) *The entity no longer does business in Maryland; or*

(c) *The entity is not subject to assessment for another reason with an explanation of that reason.*

(3) *The entity bears the burden of demonstrating it qualifies for the claimed exemption and shall submit additional documentation in support of the exemption request as required by the Board.*

(4) *While the exemption request is pending, payment of the assessment is deferred.*

(5) *The Board shall determine all requests for exemption promptly and may require additional documentation or information from the entity requesting an exemption.*

C. [The Board shall issue invoices no later than October 1, 2021, and October 1 of every year thereafter.] *Waiver of Assessment.*

(1) *An entity that is otherwise subject to assessment because it meets the definition of a qualifying entity under COMAR 14.01.01 and Health-General Article, §21-2C-11(b)(1), Annotated Code of Maryland, may request a waiver of the annual assessment by submitting a completed waiver form to the Board within 30 days of the Board transmitting the assessment invoice.*

(2) *The waiver form shall be executed under oath and:*

(a) Attest that the Prescription Drug Affordability Fund assessment exceeds 1 percent of the entity's Maryland revenue in a specified year; and

(b) Be accompanied by supporting documentation for the specified year.

(3) The entity's Maryland revenue is based on:

(a) The entity's most recent completed tax year; and

(b) The entity's total Maryland revenue.

(4) Recommended supporting documentation includes verifiable evidence of the entity's Maryland revenue for the entity's most recent completed tax year, including, but not limited to, the entity's Maryland income tax return and supporting schedules.

(5) The entity bears the burden of demonstrating it qualifies for the claimed waiver and shall submit additional documentation in support of the exemption request as required by the Board.

(6) While the waiver request is pending, payment of the assessment is deferred.

(7) The Board shall determine all requests for waiver promptly and may require additional documentation or information from the entity requesting a waiver.

**D. Collection and Penalties.**

(1) Any [bill] invoice not paid within 30 days of the payment due date may be subject to an interest penalty to be determined and collected by the Board.

(2) In addition to any penalties the Board may impose on an entity that fails to pay the fee assessed by the Board in a timely manner, the Board may also refer an entity's delinquent account to the Department of Budget and Management's Central Collection Unit, pursuant to the procedures in State Finance and Procurement Article, Title 3, Subtitle 3, Annotated Code of Maryland, and COMAR 17.01.01.

[E. In addition to any penalties the Board may impose on an entity that fails to pay the fee assessed by the Board in a timely manner, the Board may also refer an entity's delinquent account to the Department of Budget and Management's Central Collection Unit, pursuant to the procedures in State Finance and Procurement Article, Title 3, Subtitle 3, Annotated Code of Maryland, and COMAR 17.01.01.

F. The Board shall waive the fee assessment upon request by an assessed entity, provided that entity demonstrates, through attestation and supporting documentation, that the fee assessment exceeds 1 percent of that entity's revenue earned in the State during the entity's preceding fiscal year.]

**.03 Amount of Assessment.**

A. (text unchanged)

B. [As provided for in Regulation .02 of this chapter, upon demonstration that the fee assessment exceeds 1 percent of that entity's revenue in the State during their preceding fiscal year, the Board shall waive the fee assessment for that year.] *An entity may request to pay the annual assessment in installments by submitting a letter to the Board demonstrating significant financial hardship in paying the assessment in a single payment.*

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Prescription Drug Affordability Board